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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,674	10/17/2005	Kaw Yan Chua	15700.0002	1823

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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
12/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,674	CHUA ET AL.	
	Examiner	Art Unit	
	NORA M. ROONEY	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *138,173-177,180 and 181* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *138, 173-177, 180 and 181* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response filed on 09/20/2010 is acknowledged.

2. Claims 138, 173-177 and 180-181 are pending and currently under consideration as they read on a method for producing a polypeptide capable of stimulating an immune response against a molecule, the method comprising: (a) identifying a molecule against which the stimulation of the immune response is desired, the molecule consisting of a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2); and (b) forming a fusion protein by joining the molecule as a first portion thereof with a second portion being an Fve polypeptide having a sequence shown as SEQ ID NO: 6 and comprising a mutation selected from the group consisting of: a mutation from R to A at position 27 of that sequence (R27A) and a mutation from T to A at position 29 of that sequence (T29A).

3. In view of the amendments filed on 09/20/2010, only the following rejections are maintained.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 138, 173-177 and 180-181 *are* rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: a method for producing the fusion proteins

of SEQ ID NO:44 and 46 using nucleic acids, vectors and host cells, does not provide reasonable enablement for: **a method for producing a polypeptide capable of stimulating an immune response against a molecule**, the polypeptide comprising a fusion protein, the method comprising: (a) providing a host cell comprising **an expression vector containing a nucleic acid sequence encoding the fusion protein, the fusion protein comprising a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2) fused to a Fve polypeptide**; (b) expressing the encoded fusion protein; and (c) recovering the fusion protein of claim 138; wherein the fusion protein comprises **a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2)** fused to an FveR27A polypeptide comprising the amino acid sequence of SEQ ID NO: 32 of claim 173; wherein the fusion protein comprises a Der p 2-FveR27A fusion protein comprising the amino acid sequence of SEQ ID NO: 44 of claim 174; wherein the fusion protein comprises **a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2)** fused to a FveT29A polypeptide comprising the amino acid sequence of SEQ ID NO: 36 of claim 175; wherein the fusion protein comprises a Der p 2-T29A fusion protein comprising the amino acid sequence of SEQ ID NO: 46 of claim 176; wherein the polypeptide further comprises a glutathione S transferase (GST) moiety of claim 177; wherein the Fve polypeptide further comprises a mutation from R to A at position 27 of SEQ ID NO: 6 (R27A) of claim 180; wherein the Fve polypeptide further comprises a mutation from T to A at position 29 of SEQ 1D NO: 6 (T29A) of claim 181.

Applicant's argument filed on 09/20/2010 has been fully considered, but is not found persuasive.

Applicant argues:

> "Not in acquiescence to the rejection but in an effort to expedite prosecution, Applicants have amended independent claim 138 to relate to a method for producing a polypeptide capable of stimulating an immune response against a molecule, the polypeptide including a fusion protein, the method including providing a host cell comprising an expression vector containing a nucleic acid sequence encoding the fusion protein, the fusion protein including a Group 2 allergen of a house mite of species *Dermatophagoidespteronyssinus* (Der p 2) fused to a Fve polypeptide, (b) expressing the encoded fusion protein and (c) recovering the fusion protein. Accordingly, amended claim 138 now recites the necessary elements for expression of fusion proteins using nucleic acids. Applicants have also amended claim 138 and deleted reference to the phrase "having a sequence shown as." Applicants have further amended claims 173-177 to replace the phrase "in which" with "wherein."
>
> It is clear from the above that the specification describes the invention in sufficient detail to enable a person skilled in the art to make the invention. Applicants therefore submit that claim 138 and dependent claims are sufficiently enabled by the specification as filed. Applicants respectfully request reconsideration and the withdrawal of this rejection."

It is the Examiner's position that the specification discloses in the Appendix on page 165 the fusion proteins of SEQ ID NO:44 and 46 and in a method for their production in Example 13 on pages 117-121 and Figure 16.

The recitation of "a nucleic acid sequence encoding the fusion protein, the fusion protein comprising a Group 2 allergen of a house dust mite of species Dermatophagoides pteronyssinus (Der p 2) fused to a Fve polypeptide" is open language that encompasses polypeptides that may comprise subsequences and/or mutations of the recited sequences and and may further comprise any number of additional amino acids added onto the N- and/or C- terminus of the disclosed fusion portion. The specification has not adequately disclosed the genus of methods recited and it would require one or ordinary skill in the art to perform undue experimentation to perform the invention commensurate in scope with the claims.

The terms "a Group 2 allergen of a house dust mite of species Dermatophagoides pteronyssinus (Der p 2)" and "a Fve polypeptide" encompass mutants and subsequences. The

specification is not enabled for the production of the genus of molecules that comprise mutants and subsequences of the whole Der p 2 and Fve polypeptides disclosed in the specification. In addition, there is not a sufficient function disclosed whereby one of ordinary skill in the art would be able to screen for molecules that are encompassed. The recitation of being capable of stimulating an immune response against a molecule is not a sufficiently limited function that could be used for screening. Absent a sufficiently limiting function, the claims must be limited to the genus of methods that are sufficiently disclosed.

6. Claims 138, 173-177 and 180-181 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of : a method for producing the fusion proteins of SEQ ID NO:44 and 4 using nucleic acids, vectors and host cells.

Applicant is not in possession of: **a method for producing a polypeptide capable of stimulating an immune response against a molecule**, the polypeptide comprising a fusion protein, the method comprising: (a) providing a host cell comprising **an expression vector containing a nucleic acid sequence encoding the fusion protein, the fusion protein comprising a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2) fused to a Fve polypeptide**; (b) expressing the encoded fusion protein; and (c)

recovering the fusion protein of claim 138; wherein the fusion protein comprises **a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2)** fused to an FveR27A polypeptide comprising the amino acid sequence of SEQ ID NO: 32 of claim 173; wherein the fusion protein comprises a Der p 2-FveR27A fusion protein comprising the amino acid sequence of SEQ ID NO: 44 of claim 174; wherein the fusion protein comprises **a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2)** fused to a FveT29A polypeptide comprising the amino acid sequence of SEQ ID NO: 36 of claim 175; wherein the fusion protein comprises a Der p 2-T29A fusion protein comprising the amino acid sequence of SEQ ID NO: 46 of claim 176; wherein the polypeptide further comprises a glutathione S transferase (GST) moiety of claim 177; wherein the Fve polypeptide further comprises a mutation from R to A at position 27 of SEQ ID NO: 6 (R27A) of claim 180; wherein the Fve polypeptide further comprises a mutation from T to A at position 29 of SEQ 1D NO: 6 (T29A) of claim 181

Applicant's argument filed on 09/20/2010 has been fully considered, but is not found persuasive.

Applicant argues:

> "Not in acquiescence to the rejection but in an effort to expedite prosecution, Applicants have amended independent claim 138 to relate to a method for producing a polypeptide capable of stimulating an immune response against a molecule, the polypeptide including a fusion protein, the method including providing a host cell comprising an expression vector containing a nucleic acid sequence encoding the fusion protein, the fusion protein including a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2) fused to a Fve polypeptide, (b) expressing the encoded fusion protein and (c) recovering the fusion protein. Accordingly, amended claim 138 now recites the necessary elements for expression of fusion proteins using nucleic acids. Applicants have also amended claim 138 and deleted reference to the phrase "having a sequence shown as."
>
> Accordingly, the specification sufficiently describes the claimed invention in full, clear, concise and exact terms and satisfies the written description requirement of 35 U.S.C. § 112, first paragraph. Thus

Applicants respectfully request reconsideration and withdrawal of this rejection with respect to claim 138 and dependent claims thereof."

It is the Examiner's position that the specification describes in the Appendix on page 165 the fusion proteins of SEQ ID NO:44 and 46 and in a method for their production in Example 13 on pages 117-121 and Figure 16.

The recitation of "a nucleic acid sequence encoding the fusion protein, the fusion protein comprising a Group 2 allergen of a house dust mite of species Dermatophagoides pteronyssinus (Der p 2) fused to a Fve polypeptide" is open language that encompasses polypeptides that may comprise subsequences and/or mutations of the recited sequences and may further comprise any number of additional amino acids added onto the N- and/or C- terminus of the described fusion portion. The terms "a Group 2 allergen of a house dust mite of species Dermatophagoides pteronyssinus (Der p 2)" and "a Fve polypeptide" encompass mutants and subsequences. The specification has not described the production of the genus of molecules that comprise mutants and subsequences of the whole Der p 2 and Fve polypeptides described in the specification.

It remains the Examiner's position that the specification does not disclose a correlation between the structure of the fusions and their function (capable of stimulating an immune response gainst a molecule) such that a skilled artisan would have known what fusions possess the claimed functions. "Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features" *Ex parte Kubin* (83 U.S.P.Q.2d 1410 (BPAI 2007)), at page 16. In this instant case, Applicants have not provided the requisite identifying structural features of the genus of fusions

encompassed. "Without a correlation between structure and function, the claim does little more than define the claimed invention by function" *supra*, at page 17.

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 6, 2010

/Nora M Rooney/

Primary Examiner, Art Unit 1644